

### **REMARKS**

Claims 1, 4, 6-7, 10, 13-14, 16, and 18-19 remain pending in this application, of which claims 8-9 are withdrawn. In view of the foregoing amendments and following comments, Applicants respectfully request reconsideration and allowance of all pending claims.

Applicants traverse the rejection of claims 1, 4, 6, 10, 13, 16, and 18 under 35 U.S.C. 103(a) as obvious over Kenigsberg (U.S. Patent No. 4,168,703). Independent claims 1, 10, and 16 as amended, as well as the claims dependent directly or indirectly thereon, specify a device for measuring blood pressure in a vascular structure. The device includes a tubular sheath sized for insertion into the vascular structure. In addition, wherein the blood pressure measuring device has a distal portion that is inserted into the vascular structure, and an exterior surface of the distal portion of the blood pressure measuring device has a cross-sectional profile of a single circle. It is not seen that the cited prior art discloses or suggests an intravascular blood pressure measuring device having such a size and profile.

Instead, Kenigsberg discloses a diagnostic tool intended for insertion into the gastroesophageal tract for measuring gastroesophageal reflux. As such, Kenigsberg teaches that the device must continuously measure the pressure present on opposite sides of the sphincter, namely the lower esophagus and stomach, as well as selectively measuring the pressure present at various points between the two. (Kenigsberg, column 1, line 66 to column 2, line 3). To achieve this, Kenigsberg teaches the use of three separate conduits, which are a sheath 12, a first reference member 32, and a second reference member 38. A series of openings 20 are formed in the sheath 12 and a movable probe 22 is inserted into the sheath 12 to communicate a selected opening 20 with a proximal end of the probe, thereby to selectively measure a pressure between

the stomach and lower esophagus. The first reference member 32 extends substantially the length of the sheath 12 and has an opening at a distal end to communicate stomach pressure to a proximal end of the member 32. The second reference member 38 extends only partially along the length of the sheath 12 and has an opening at a distal end to communicate lower esophagus pressure to a proximal end of the member 38. In use, portions of the sheath 12, first reference member 32, and second reference member 38 are inserted through the nose or mouth and into the stomach. The portion inserted into the patient has an irregular profile consisting of a cluster of tubes

There is no motivation to modify the Kenigsberg device to arrive at the claimed blood pressure measuring device. First, Kenigsberg is directed to a device for measuring gastroesophageal reflux. There is no suggestion or motivation to modify it for use within a vascular structure. In addition, the pressure sensing means disclosed in Kenigsberg is unsuitable for use in an intravascular device. The only "pressure sensitive means" disclosed in Kenigsberg is a strain gauge that is attached to the ends of the probe 22, and reference members 32 and 38 to measure the resistance to the outflow of infused water from the tool 10 and into the gastroesophageal track 44. (Kenigsberg, column 4, lines 45-51) Accordingly, the pressure sensing means of Kenigsberg requires introduction of an outside fluid to infer pressure, which is unsuitable for use in intravascular applications.

Similarly, there is no motivation to modify the Kenigsberg tool to provide a distal portion having with an exterior surface having a cross-sectional profile of a single circle as claimed. Instead, Kenigsberg clearly states that it is necessary to measure the esophagus and stomach pressures, and therefore it must include the first and second reference members 32, 38 in addition

to the sheath 12. Removing the reference members 32, 38 to improve the profile of Kenigsberg would render it unusable for its intended purpose of measuring gastroesophageal reflux, and therefore there can be no suggestion or motivation for such a proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

It is important to note that the current claims specify that the blood pressure measuring device as a whole has a distal portion with a cross-sectional profile of a single circle, and not simply one of its constituent components. The Examiner has argued that the movable probe 22 disclosed at column 3, line 18, is responsive to this element because it is described as a hollow tube. The probe 22, however, is merely one component of the overall tool 10, and it does not define an exterior surface of the tool 10 because it is inserted into the sheath 12. Instead, the distal portion of the tool 10 has an exterior surface profile of at least two circles, one for the sheath 12 and one for the first reference member 32, as best illustrated in Fig. 2. Consequently, Kenigsberg fails to disclose or suggest this element of the claims.

Applicants traverse the rejection of claims 7, 14, and 19 under 35 U.S.C. 103(a) as obvious over Kenigsberg in view of Zarychta et al. (U.S. Patent No. 6,259,938). Claims 7, 14, and 19 depend from independent claims 1, 10, and 16, respectively. Zarychta et al. fail to disclose or suggest the deficiencies noted above with respect to Kenigsberg, and therefore this rejection must also be withdrawn.

**CONCLUSION**

It is submitted that the present application is in good and proper form for allowance. A favorable action on the part of the Examiner is respectfully solicited.


If, in the opinion of the Examiner a telephone conference would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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